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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,378	07/14/2003	Steven Walkley	2543-1-022PCT/CIP	5426
23565	7590	08/08/2007		
KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			EXAMINER SULLIVAN, DANIEL M	
			ART UNIT	PAPER NUMBER
			1636	
			MAIL DATE	DELIVERY MODE
			08/08/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/619,378	<b>Applicant(s)</b> WALKLEY, STEVEN	
	<b>Examiner</b> Daniel M. Sullivan	<b>Art Unit</b> 1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21,22,28,29 and 36-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21,22,28,29 and 36-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This Non-Final Office Action is a reply to the Paper filed 4 May 2007 in response to the Non-final Office Action mailed 30 October 2006. Claims 21, 22, 25, 26, 28, 29, 32, 33, 36 and 37 were considered in the 30 October Office Action. Claims 25, 26, 32 and 33 were cancelled, claims 21, 22, 28, 29, 36 and 37 were amended and claims 38 and 39 were added in the 4 May Paper. Claims 21, 22, 28, 29 and 36-39 are pending and under consideration.

#### *Response to Amendment and Arguments*

##### Specification

Objection to the specification as lacking antecedent basis for the claimed subject matter is **withdrawn** in view of the amendment of the claims to recite “mucopolysaccharidosis” disease.

##### Claim Rejections - 35 USC § 112

Rejection of claims 21, 36 and 37 under 35 U.S.C. 112, second paragraph, as being indefinite is **withdrawn** in view of the amendment of the claims to recite “mucopolysaccharidosis” disease.

##### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Rejection of claims 21, 22, 29, 29, 36 and 37 under 35 U.S.C. 102(e) as being anticipated by Fan et al. U.S. Pub. No. 2002/0035072 A1 is **withdrawn** in view of Applicant's arguments.

In particular, all of the teachings of Fan et al. with respect to the use of N-butyl-1-deoxygalactonojirimycin are directed to treatment of Fabry disease. Fan et al. does not teach the treatment of a mucopolysaccharidosis disease using N-butyl-1-deoxygalactonojirimycin.

Claims 21, 22, 28, 29, 36 and 37 **stand rejected** and newly added claims 38 and 39 **are rejected** under 35 U.S.C. 102(e) as being anticipated by Meeker et al. U.S. Pub. No. 2002/0095135. This rejection is maintained for the reasons set forth in the 30 October Office Action (pp. 5-6) and herein below in the response to Applicant's arguments. With respect to claims 38 and 39, the claims are the same as previously rejected claims 21 and 22 except that the inhibitor of glucosylceramide synthase is limited to N-butyldeoxygalactonojirimycin. As Meeker et al. teaches N-butyldeoxygalactonojirimycin as an embodiment of the method contemplated therein (see especially paragraph 0048) the method of claims 38 and 39 are also anticipated by the teachings of Meeker et al.

#### *Response to arguments*

In response to the *prima facie* rejection of record, Applicant contends that Meeker et al. does not qualify as prior art under 35 USC §102(e) because the Meeker et al. application is not entitled to the priority of this earlier filing for the disclosure of the present invention. Applicant argues that the disclosure relied upon by the Examiner was first made at the filing date of United

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States Pub No. 200210095 135 (June 19, 2001) and because the present application is entitled to a priority date of January 12, 2001, by virtue of priority document U.K. Application No. 0100889.5 (hereinafter, the U.K. application), the Meeker et al. application fails to meet the criteria established for a prior art reference under 102(e) because it does not disclose the instant invention prior to Applicant's own invention of the same.

This argument has been fully considered but is not persuasive. Even if one accepts that the Meeker et al. publication is not entitled to benefit of the provisional application, the 12 June 2001 filing date of the Meeker et al. application antedates the effective filing date of the instant application because the claims of the instant application are not entitled to benefit of the U.K. application. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The priority application includes no explicit teaching that NB-DNJ or NB-DGJ should be used in a method of treating mucopolysaccharidosis disease as recited in the instant claims. With regard to treating mucopolysaccharidosis disease, the U.K. application teaches:

“[T]he use of **a compound of the invention** in the manufacture of a medicament for the treatment of mucopolysaccharidosis type I, mucopolysaccharidosis type IIID, mucopolysaccharidosis type IIIA, mucopolysaccharidosis type VI and mucopolysaccharidosis type VII.” (Page 10, lines 11-15; emphasis added.); and,

“[A] method for the treatment of mucopolysaccharidosis type I, mucopolysaccharidosis type IIID, mucopolysaccharidosis type IIIA, mucopolysaccharidosis type VI and mucopolysaccharidosis type VII which comprises the step of administering to a patient an effective amount of **a compound of the invention...**” (Page 11, lines 30-34; emphasis added.)

The specification further teaches, “Thus, **the compounds of the invention** exhibit less inhibitory action against both glucosidases and galactosidases (thereby reducing side effects) **than compounds such as NB-DNJ or NB-DGJ**, while retaining activity against glucosylceramide synthases.”

First, the teachings of the U.K. application do not contemplate treatment of species such as mucopolysaccharidosis type IH, IS, IH/S, IIIB, IIIC or IV. Therefore, claims 22, 29 and 39 are clearly not supported by the disclosure of the U.K. application. Furthermore, the U.K. application plainly distinguishes compounds such as NB-DNJ or NB-DGJ from “the compounds of the invention” which are contemplated for use in the treatment of mucopolysaccharidosis disease and actually teaches away from using NB-DNJ and NB-DGJ in favor of “the compounds of the invention”. Therefore, one of skill in the art would conclude that the U.K. application does not disclose a method of treating mucopolysaccharidosis disease comprising administering NB-DNJ or NB-DGJ as presently claimed in a manner sufficient to satisfy the requirements of 35 USC §112, first paragraph.

Applicant further contends that the teachings of Meeker et al. do not anticipate the claims of the instant application because Meeker et al. do not teach a therapeutic approach that calls for administration of only small molecule therapy (e.g., imino sugar inhibitors of glucosylceramide synthase) for the treatment of any lysosomal storage disease. Meeker et al. teach combination

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therapy. By extension, therefore, Meeker et al. also fail to teach a therapeutic approach directed to administration of only imino sugar inhibitors of glucosylceramide synthase for the treatment of mucopolysaccharidosis diseases.

This argument has been fully considered but is not persuasive, at least, because the claims of the instant application do not require that “only” imino sugar inhibitors of glucosylceramide synthase be administered. Instead, the claims are directed to a method that comprises administering NB-DNJ or NB-DGJ. Therefore, the scope of the claims embraces any method wherein NB-DNJ or NB-DGJ is administered to a patient suffering from mucopolysaccharidosis disease, irrespective of what is administered in conjunction with said NB-DNJ or NB-DGJ.

Applicant’s arguments have been fully considered but are not deemed persuasive in view of the record as a whole. Therefore, the claims stand properly rejected under 35 USC §102(e) as anticipated by the art.

### *New Grounds*

#### Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22, 29 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The claims are indefinite in reciting “(MPS IH, IS or IH/S)” it is unclear whether the parenthetical recitation of these limitations is intended to limit MPSI to only the recited species or whether the recited species are intended as only examples of MPSI. In view of this, a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement. Therefore, a rejection of the claim under 35 U.S.C. 112, second paragraph, is appropriate.

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21, 28 and 36-38 rejected under 35 U.S.C. 102(b) as being anticipated by Dwek et al. WO 00/62779 (made of record in the IDS filed 15 January 2004).

Dwek et al. contemplates treating patients having mucopolysaccharidosis disease by administering the imino sugar inhibitors of glucosylceramide synthase N-butyldeoxynojirimycin and N-butyldeoxygalactonojirimycin. (See especially, the abstract; page 4, lines 13 and 20-21; page 7, lines 11-19; and the paragraph bridging pages 10-11.) Absent evidence to the contrary, the method of treating mucopolysaccharidosis diseases through the administration of inhibitors of glucosylceramide synthase would result in the outcomes recited in the instant claims. Thus, the teachings of Dwek et al. anticipate the invention of independent claims 21, 28-38. Therefore, the claims are properly rejected under 35 USC §102(e) as anticipated by Dwek et al.



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22, 29, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dwek et al. (*supra*), as applied to claims 21, 28 and 38 above, further in view of Danos et al. (1995) *Mol. Cell Biol. Hum. Dis.* 5:530-567.

As described above, Dwek et al. teaches a method of treating mucopolysaccharidosis according to the limitations of the instant claims 21, 28 and 38. Dwek et al. does not specifically identify the MPS conditions recited in claims 22, 29 and 39.

Table 17.1 of Danos et al. shows that the various conditions recited in claims 22, 29 and 39 were recognized in the art as forms of mucopolysaccharidoses at the time that Dwek et al. was published.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to treat any of the art recognized forms of mucopolysaccharidosis, such as those taught by Danos et al., according to the teachings of Dwek et al. One would be motivated to combine the teachings of the prior art because Danos et al. teaches that bone marrow transplantation has been used with some success in MPS patients (see especially the second full paragraph on page 355) and Dwek et al. teaches that co-administration of NB-DNJ with bone marrow transplantation provides a synergistic increase in the rate of neuronal glycolipid degradation.

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(See especially the sentence bridging pages 3-4.) Absent evidence to the contrary, one would also have a reasonable expectation of success because Dwek et al. is teaching treatment using a combination of NB-DNJ or NB-DGJ and, *inter alia*, bone marrow transplantation and Danos et al. teaches that bone marrow transplantation was already recognized as having therapeutic benefit in mucopolysaccharidoses at the time Dwek et al. was published.

In view of the foregoing, the claimed invention, as a whole, would have been obvious to one of ordinary skill in the art at the time the invention was made. Therefore, the claims are properly rejected under 35 USC § 103(a).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M. Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel M Sullivan/  
Primary Examiner  
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